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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,061	10/06/2000	Stephen H. Bartelmez	0450-0031.30	2847

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10/07/2003

Iota Pi Law Group
P O Box 60850
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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/07/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Flb

Office Action Summary	Application No. 09/684,061	Applicant(s) Bartelmez et al	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 21, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 10, 17, 19, 21, and 22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 22 is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 10, 17, and 21 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

File

Application/Control Number: 09/684,061

Page 2

Art Unit: 1635

DETAILED ACTION

This Office action is in response to the communication filed July 21, 2003, Paper No. 22.

Claims 1, 3-6, 10, 17, 19, 21 and 22 are pending in the instant application.

Response to Arguments and Amendments

Any rejections not repeated in this Office action are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 17 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions and methods comprising the administration of an antisense oligonucleotide that targets and inhibits the expression of an Evi-1 zinc finger gene. The specification and claims do not describe the elements that are essential to the definition of an Evi-

Art Unit: 1635

1 zinc finger gene, which elements include naturally occurring regulatory elements, untranslated regions and/or those elements which mediate the expression of the gene in a particular cell type, and which elements are empirically determined and not disclosed, nor does the specification describe the elements essential to the genus comprising a sequence spanning a mRNA translational start codon of a human Evi-1 zinc finger gene. The disclosure does not clarify or adequately describe the members of the genera comprising an Evi-1 zinc finger gene, or a sequence spanning a mRNA translational start codon thereof. The scope of the claims includes numerous structural variants (e.g. includes alternatively spliced Evi-1 zinc finger genes) and the genera are highly variant because a significant number of structural differences between members of the genera is permitted. Concise structural features that could distinguish members of the genera from others is missing from the disclosure. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the various genera claimed. Thus, Applicant was not in possession of the claimed genera.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1635

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitani et al in view of Baracchini et al.

The claims are drawn to antisense oligonucleotides which target the translational start codon of an Evi-1 zinc finger gene, and which antisense comprise morpholino modifications and have a substantially uncharged backbone.

Mitani et al teach a composition comprising an antisense oligonucleotide that targets mRNA encoding a Evi-1 zinc finger gene, which gene is preferentially expressed in stem cells (See entire text, especially the introduction on page 711).

Mitani et al do not teach antisense oligonucleotides that target the initiation codon region of a nucleic acid encoding a Evi-1 zinc finger gene, and which antisense oligonucleotide comprises morpholino moieties.

Baracchini et al teach antisense oligonucleotides that target the initiation codon region of a target mRNA of known nucleic acid sequence in vitro, and which antisense oligonucleotides

Art Unit: 1635

comprise morpholino moieties, which modification substantially reduces the charge of the oligonucleotide backbone (See column 6, lines 35-57; column 9, line 6 - column 10, line 25).

It would have been obvious to one of ordinary skill to design and utilize antisense oligonucleotides that target an initiation region of a target gene of known nucleic acid sequence in vitro because Baracchini et al teach the targeting of the initiation region of a target gene of known nucleic acid sequence comprising the administration of antisense oligonucleotides in vitro, whereby target gene expression is inhibited. One of ordinary skill in the art would have been motivated to target and inhibit the expression of Evi-1 zinc finger genes because Mitani et al teach the inhibition of expression of an Evi-1 zinc finger gene in vitro comprising the administration of antisense oligonucleotides, and Mitani et al teach the correlation of Evi-1 zinc finger gene expression and chronic myelocytic leukemia (e.g. see introduction of Mitani et al on page 711). One of ordinary skill in the art would have expected that the targeting of the initiation region of a target gene of known nucleic acid sequence using antisense oligonucleotides would inhibit the expression of that target gene in vitro. One of ordinary skill in the art would have been motivated to incorporate morpholino modifications into an antisense oligonucleotide because Baracchini et al teach the incorporation of such residues into antisense to enhance target binding, cellular uptake and oligonucleotide stability. One of ordinary skill in the art would have been motivated to target the initiation region of the Evi-1 zinc finger gene in order to inhibit Evi-1 zinc finger expression because it was taught previously by Mitani et al that aberrant expression of Evi-1 has been associated with chronic myelocytic leukemia. It would have been obvious to one of ordinary

Art Unit: 1635

skill in the art to incorporate modifications into antisense oligonucleotides such as morpholino moieties because such modifications have been successfully incorporated into antisense oligonucleotides for enhancing cellular uptake and increasing nuclease resistance.

Therefore the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19 and 22 appear free of the prior art of record.

A handwritten signature in black ink, appearing to read 'R. Shukla', with a long horizontal line extending to the right.

**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**

Art Unit: 1635

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

October 3, 2003